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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,783	10/29/2003	Richard Warby	WARB3001/REF	6091
<div>23364 7590 05/09/2007</div> <div>BACON & THOMAS, PLLC</div> <div>625 SLATERS LANE</div> <div>FOURTH FLOOR</div> <div>ALEXANDRIA, VA 22314</div>				
<div>EXAMINER</div> <div>DRODGE, JOSEPH W</div>				
<div>ART UNIT PAPER NUMBER</div> <div>1723</div>				
<div>MAIL DATE DELIVERY MODE</div> <div>05/09/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/694,783	Applicant(s) WARBY, RICHARD	
	Examiner Joseph W. Drodge	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-47 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36,37,42 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by DeCrosta et al (hereafter referred to as DeCrosta) patent 5,550,211. DeCrosta discloses a method of cleaning/purifying elastomeric and rubber polymers for articles for medical and pharmaceutical use including contacting the articles with aliphatic alcohols and consequently discloses the corresponding apparatus/articles and method of making the claimed articles. This encompasses: preparation of (forming of) gaskets (i.e. seals) and valves employed in manufactured pharmaceutical dispensing devices (column 1, lines 13-23 and column 2, lines 28-32); providing an elastomeric composition that may be a butyl rubber or include isobutyl materials (column 3, lines 1-6 and column 5, lines 17-22); initiating a cross-linking reaction (column 3, lines 5-10), and contacting the gasket or seal with an alcohol solvent to remove impurities by extraction (column 4, lines 14-18, 33-35, 45-47, impurities removed include residual cross-linking agents (column 3, lines 5-6), waxes (column 5, lines 24-26) and accelerators/process aids (column 1, lines 24-27). The instant claims do not preclude the solvent being applied as a supercritical fluid as disclosed by DeCrosta. For claims 37,40,43 and 46 the alcohol may be ethanol (column 4, line 46).

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DeCrosta also discloses the extracting solvent to be applied with "refluxing" or "percolating" as the claims are now amended. In column 3, lines 50-64, the solvent is described as passing through a cylindrical cell holding the seals being treated and under pressure, with solvent and collected impurities being then passed out of the cell and a surrounding chamber under controlled back-pressure.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 39,40,45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Thomas patent 6,234,362. Impurities removed in DeCrosta include residual cross-linking agents (column 3, lines 5-6), waxes (column 5, lines 24-26) and accelerators/process aids (column 1, lines 24-27) used in product manufacturing.

Claims 39,40,45 and 46 differ in requiring the elastomeric rubber polymer to be isobutylene or co-polymer thereof. Thomas teaches such at column 1, lines 44-54. It

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would have been obvious to one of ordinary skill in the art to have selected isobutylene or copolymer as the elastomer used in DeCrosta in view of the superior sealing properties and extended shelf life of products comprising isobutylene.

Claims 38 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Cripps or newly cited Adjei et al (Adjei) patent 6,596,261.

Claims 38 and 44 differ from DeCrosta in requiring a compression or injection moulding step in the manufacture of the seal. However, Cripps teaches moulding at paragraph 134, as does Adjei at column 10, lines 42-62. It would have also been obvious to employ moulding in the manufacture of the DeCrosta seals, to enable efficient manufacture of the articles and to allow use of fewer components in the finished articles, by producing integrally combined components.

Claims 41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCrosta in view of Thomas patent 6,234,362 as applied to claims 39 and 45 above, and further in view of Adjei or Cripps. Claims 38 and 44 differ from DeCrosta in requiring a compression or injection moulding step in the manufacture of the seal. However, Cripps teaches moulding at paragraph 134, as does Adjei at column 10, lines 42-62. It would have also been obvious to employ moulding in the manufacture of the DeCrosta seals, to enable efficient manufacture of the articles and to allow use of fewer components in the finished articles, by producing integrally combined components.

Applicant's arguments filed on March 20, 2007 have been fully considered but they are not persuasive.

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It is argued that the claims rely on a refluxing alcohol solvent instead of supercritical fluids. Although the DeCrosta cleaning solvent is in supercritical form, it is considered to reflux through a cylindrical cell holding the seal articles being cleaned, in that the extracting solvent passes through a cell holding the articles from which impurities are collected and under controlled back pressure (column 3, lines 50-65 of DeCrosta). The claims do not preclude the solvent being in supercritical state.

It is asserted that DeCrosta is primarily concerned with nitrile rubber products; use of "butyl rubbers" is explicitly disclosed at column 3, line 1.

It is argued that DeCrosta teaches away from "refluxing" at columns 1-2 of the patent as an unacceptable procedure which deals primarily with the outer surface of the article. Firstly, neither the instant claims or specification describe which portion of the subject seals are cleaned or purified, "refluxing" does not equate with cleaning the interior portions of articles. What is taught away from at column 1, line 53-column 2, line 2 of DeCrosta is the use of conventional fluorocarbon, or specifically "Freon" type, cleaning solvents.

It is argued that Thomas refers to EPDM, not isobutylene polymeric rubbers. However, Thomas at column 1, lines 48-53 teaches valve seals of a material of isobutylene.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steve Griffin, can be reached at 571-272-1189. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

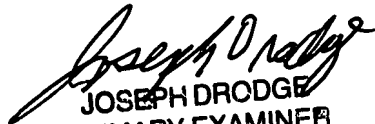
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JWD

May 2, 2007


JOSEPH DRODGE
PRIMARY EXAMINER